

Stuber, Robyn

From: McNaughton, Eugenia
Sent: Monday, March 17, 2014 8:43 AM
To: Spears, Renee@Waterboards
Cc: Denton, Debra; Smith, DavidW; Stuber, Robyn; Sakamoto, Roseanne; Remaley, Steve
Subject: RE: Alternative Test Procedure Request for Use of Two-Concentration Test Design When Using Test of Significant Toxicity Hypothesis Testing Approach
Attachments: CASWRCBTSTATP3172014.pdf

Hi Renee

Here is our response to your request for a California-wide ATP to use the TST to evaluate toxicity tests in compliance with NPDES permits for all non-oceanic surface waters. I am assuming that you will inform the appropriate offices and regional boards.

Best to you,

Eugenia

From: Spears, Renee@Waterboards [<mailto:renee.spears@waterboards.ca.gov>]
Sent: Thursday, February 13, 2014 9:19 AM
To: McNaughton, Eugenia
Cc: Bishop, Jonathan@Waterboards; Whitney, Vicky@Waterboards; Crader, Phillip@Waterboards; Breuer, Rich@Waterboards; Rasmussen, Rik@Waterboards; Ogg, Brian@Waterboards
Subject: Alternative Test Procedure Request for Use of Two-Concentration Test Design When Using Test of Significant Toxicity Hypothesis Testing Approach



February 12, 2014

Eugenia McNaughton, Ph.D., Chief
Quality Assurance Office
U.S. Environmental Protection Agency, Region 9
75 Hawthorne Street
San Francisco, CA 94105

Dear Dr. McNaughton:

Pursuant to Code of Federal Regulations, title 40, section 136.4, the State Water Resources Control Board (State Water Board) is submitting this application for US EPA Region 9 review and approval of the statewide Alternate Test Procedure use of a two-concentration test design when using the Test of Significant Toxicity (TST) hypothesis testing approach.

State Water Board staff is developing an amendment to the Water Quality Control Plan for Enclosed Bays and Estuaries of California that will standardize the regulation of aquatic toxicity for all non-oceanic surface waters. The United States Environmental Protection Agency's (US EPA) TST hypothesis testing approach (US EPA 2010) is an essential component of this proposed toxicity amendment as it forms the basis for the numeric water quality objective and acts as the primary means of determining compliance with the effluent limitations.

Toxicity tests are vital tools used to measure the aggregate effects of pollutants, detect unknown toxicants, and assess their bioavailability in a more effective manner than that of pollutant-specific tests and bioassessments. Test methods developed for both freshwater and marine organisms, are divided between acute and chronic endpoints. Acute toxicity tests measure lethality, while chronic toxicity tests focus on sub-lethal effects, such as reductions in growth and reproduction. Currently, toxicity tests are used to determine compliance with the narrative objectives for toxicity established in the Regional Water Quality Control Plans (Basin Plans). Section 4 of the Policy for Implementation of Toxics Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California (State Implementation Policy or SIP) establishes minimum chronic toxicity requirements for implementing these narrative water quality objectives for toxicity. However, discrepancies persist among the toxicity requirements included in National Pollutant Discharge Elimination System (NPDES) permits and Waste Discharge Requirements (WDR). The draft toxicity amendment seeks to create a uniform regulatory framework to address these inconsistencies through the required use of the TST for all NPDES wastewater and point source WDR dischargers in California.

Use of the TST does not alter the test procedures used to produce the biological endpoints of US EPA's toxicity test methods (e.g. organism age, food, temperature, exposure length); it merely alters the minimum number of test concentrations required for toxicity testing.

The benefits of the TST approach have been lauded by numerous academicians. The five peer reviewers selected in a blind fashion for US EPA's peer review process agreed that the TST's bioequivalence approach is sound and that the results of TST analyses are reasonable and defensible. The State Water Board also initiated a peer review focusing on the use of the TST approach in the draft Policy for Toxicity Assessment and Control (the previous iteration of the toxicity amendment). The two researchers, Dr. Gerald A. Le Blanc and Dr. Michael C. Newman, concluded that the TST is a "...major advance from the currently compromised No Observed Effects Concentration (NOEC) approach," and "...is statistically sound, reduces burden associated with the assays, and, by structuring the assay around a hypothesis of significant toxicity, provides incentive for precision in assay performance." In addition, four individual articles examining the TST approach have been published in two respected, peer-reviewed toxicological journals (Denton et al. 2011, Diamond et al. 2011, Zheng et al. 2012, Diamond et al. 2013), while the State Water Board published a report (State Water Board 2011-please see attachment) comparatively analyzing the results of over 3,000 toxicity tests using both the TST and traditional hypothesis approaches. Although this "test drive" analysis showed that the results of the NOEC and TST are generally the same, it is important to note that the TST correctly identified truly non-toxic samples more often than the NOEC did. Moreover, the NOEC failed to identify more truly toxic samples than the TST approach.

The TST approach is currently being used to implement Tribal and Territory NPDES permits issued by US EPA Region 9, as well as the US EPA Region 9 offshore oil and gas general permit (No. CAG280000). The State Water Board has included provisions requiring the use of the TST approach in the Caltrans general permit for storm water discharges (Order No. 2012-0011-DWQ), the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064), the San Diego Regional Water Quality Control Board's general permit for discharges from boatyards and boat maintenance and repair facilities (Order No. R9-2013-0026), and the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064). The TST approach has also been incorporated into several NPDES permits in Hawaii.

The State Water Board is confident that the use of the TST will strengthen toxicity regulation throughout California. Apart from improving the statistical power of toxicity test methods, the TST is simpler to use than either traditional hypothesis test methods or point estimates. In addition, the two-concentration test design will reduce the cost of toxicity monitoring for most wastewater dischargers in California. For these, and the other reasons discussed previously in this letter, the State Water Board requests that US EPA Region 9 review and approve the use of a two-concentration test design for TST-based analyses of the whole effluent toxicity testing methods promulgated in Code of Federal Regulations, title 40, section 136.3.

Sincerely,



Renee Spears
Quality Assurance Officer

cc: (via e-mail)

Jonathan Bishop, Chief Deputy Director
State Water Resources Control Board

Victoria Whitney, Deputy Director
Division of Water Quality
State Water Resources Control Board

Phillip Crader, Assistant Deputy Director Division of Water Quality
State Water Resources Control Board

Rich Breuer, Assistant Deputy Director
Office of Information Management
State Water Resources Control Board

Rik Rasmussen, Section Chief
TMDL Section
State Water Resources Control Board

Brian Ogg, Environmental Scientist
Inland Planning Standards and Implementation Unit
State Water Resources Control Board

References:

Denton DL, Diamond JM, Zheng L. 2011. Test of Significant Toxicity: A Statistical Application for Assessing Whether Effluent or Site Water is Truly Toxic. *Environmental Toxicology and Chemistry*. DOI: 10.1002/etc.493.
<http://onlinelibrary.wiley.com/doi/10.1002/etc.493/full>

Diamond JM, Denton DL, Roberts Jr. JW, Zheng L. 2013. Evaluation of the Test of Significant Toxicity for Determining the Toxicity of Effluents and Ambient Water Samples. *Environmental Toxicology and Chemistry*. DOI: 10.1002/etc.2166.
<http://onlinelibrary.wiley.com/doi/10.1002/etc.2166/full>

Diamond J, Denton D, Anderson B, Phillips B. 2011. It is time for changes in the analysis of whole effluent toxicity data. *Integrated Environmental Assessment and Management*. DOI: 10.1002/ieam.278.
<http://onlinelibrary.wiley.com/doi/10.1002/ieam.278/full>

Regional Water Quality Control Board, San Diego Region. 2013. General Waste Discharge Requirements for Discharges from Boatyards and Boat Maintenance and Repair Facilities Adjacent to Surface Waters within the San Diego Region. Order No. R9-2013-0026.

http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0026.pdf

Regional Water Quality Control Board, San Diego Region. 2013. Waste Discharge Requirements for the United States Department of the Navy Naval Base, San Diego Complex, San Diego County. Order No. R9-2013-0064.

http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0064.pdf

State Water Resources Control Board. 2011. *Effluent, Stormwater, and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST)*.

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/final_testdrive.pdf

State Water Resources Control Board. 2012a. Policy for Toxicity Assessment and Control, Public Review Draft.

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/draft_tox_policy_0612.pdf

State Water Resources Control Board. 2012b. National Pollutant Discharge Elimination System (NPDES) Statewide Storm Water Permit Waste Discharge Requirements (WDRS) for State of California Department of Transportation. Order No. 2012-0011-DWQ.

http://www.swrcb.ca.gov/board_decisions/adopted_orders/water_quality/2012/wqo2012_0011_dwq.pdf

State Water Resources Control Board peer review:

Gerald A. LeBlanc, PhD

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/gerald_leblanc_review.pdf

Michael C. Newman, PhD

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/michael_newman_review.pdf

U.S. Environmental Protection Agency. 2010. National Pollutant Discharge Elimination System Test of Significant Toxicity Technical Document. EPA 833-R-10-004.

<http://www.epa.gov/npdespub/pubs/tst-techdoc.pdf>

U.S. Environmental Protection Agency. 2012. Authorization to Discharge Under The National Pollutant Discharge Elimination System for Oil and Gas Exploration, Development, and Production Facilities. General Permit No. CAG280000.

<http://www.epa.gov/region9/water/npdes/pdf/ocs-general-permit2012.pdf>

U.S. Environmental Protection Agency peer review:

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/tst_peerreview.pdf

Zheng L, Diamond JM, Denton DL. 2012. Evaluation of whole effluent toxicity data characteristics and use of Welch's test in the Test of Significant Toxicity analysis.

<http://www.ncbi.nlm.nih.gov/pubmed/23172744>

***** ATTACHMENT NOT DELIVERED *****

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which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

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For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

***** ATTACHMENT NOT DELIVERED *****



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

March 17, 2014

Rence Spears
Quality Assurance Officer
State Water Resources Control Board
1001 I Street
Sacramento CA 95814

Dear Ms. Spears:

This letter address the State Water Resources Control Board (State Water Board) request of February 12, 2014 to use the two –concentration test design to evaluate toxicity tests using the Test of Significant Toxicity (TST) hypothesis to comply with the Code of Federal Regulations, title 40, section 136.3 and 136.5. The EPA Region 9 Quality Assurance Office (QAO) has reviewed your request, justification and supporting documentation.

I am pleased to inform you that we have determined that the State Water Board's proposed use of the two-concentration toxicity test evaluated using the Test of Significant Toxicity (TST) is an acceptable equivalent under the ATP process to the five-concentration test evaluated using NOEC-LOEC hypothesis testing recommended in 40 CFR Part 136.5. While the results of the TST should generally be similar to those of the NOEC-LOEC test, it improves understanding of discharge condition by correctly identifying toxic and non-toxic samples more often than when using the latter. In summary, we agree that when using the TST statistical approach, the use of the two-concentration is an appropriate test design.

Please note that approval is in this case state-wide, that is, it will apply to all new or revised NPDES permits issued by the State Water Board and Regional Water Quality Control Boards and any EPA-issued California permits that include whole effluent toxicity testing provisions.

Please contact me (415-972-3411) if you have further questions.

Sincerely,

A handwritten signature in cursive script that reads "Eugenia McNaughton".

Eugenia McNaughton, Ph.D.
Manager, Quality Assurance Office